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HL

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/171,885	10/28/98	CUBICCIOTTI R	BDA-0038

HM12/1110

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EXAMINER	
WARE, T	
ART UNIT	**PAPER NUMBER**
1615	7

DATE MAILED: 11/10/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/171,885	Applicant(s) CUBICCIOTTI, ROGER S.	
	Examiner Todd D Ware	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

1)☒ Responsive to communication(s) filed on *23 August 1999* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2,4,6 and 8-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2, 4, 6, 8-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☐ All b)☐ Some * c)☐ None of the CERTIFIED copies of the priority documents have been:

1.☐ received.

2.☐ received in Application No. (Series Code / Serial Number) _____ .

3.☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

14) ☐ Notice of References Cited (PTO-892)
15) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
16) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
17) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
18) ☐ Notice of Informal Patent Application (PTO-152)
19) ☐ Other: .

DETAILED ACTION

Receipt is acknowledged of response and amendment filed 8/23/99. Claims 1, 3, 5, and 7 have been deleted. New claims 9-13 have been added and claims 2, 4, 6, and 8 have been amended to depend from the newly added claims. Claims 2, 4, 6, and 8-13 are pending.

Specification

1. The amendment filed 8/23/99 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the proviso that the synthetic receptor is not a polypeptide derived from a naturally occurring protein to which the drug binds.

Applicant is required to cancel the new matter in the reply to this Office action.

Claim Rejections - 35 USC § 112

2. Claims 2, 4, 6, and 8-13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a synthetic receptor and a drug that binds to the synthetic receptor, does not reasonably provide enablement for the proviso that the synthetic receptor is not a polypeptide derived from a naturally occurring protein to which the drug binds. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The

specification teaches that the synthetic receptor may be a naturally occurring polypeptide and does not provide any teaching as to why it should not be, such as a demonstration of unexpected results.

Claim Rejections - 35 USC § 102

3. The rejections under 35 U.S.C. 102(b) are withdrawn.

Claim Rejections - 35 USC § 103

4. The text of those sections of Title 35, U.S. Code 103 not included in this action can be found in a prior Office action.

5. Claims 2, 4, 6, and 8-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morgen, Jr. et al. ('713). '713 teaches drug/carrier complexes and a method of administering a drug via a drug/carrier complex where a drug binds non-covalently to a polymeric carrier to form a prodrug complex that is capable of allowing drug dissociation from the polymeric carrier such that the drug retains its ability to bind to a site on or within a target cell. Furthermore, a biologic structure, such as an antibody, may be coupled to this complex and the carriers may bind more than one drug (abstract, and column 1, lines 9-15 and column 2, lines 28-63). The statement, "Drug activity also is preserved in vivo after administration of the conjugate to a human or mammalian host" (column 2, lines 61-63) in '713 teaches that the drug's affinity for the polymeric receptor is less than that for its pathophysiologic receptor. Applicants have attempted to amend

around the prior art with the proviso that "the synthetic receptor is not a polypeptide derived from a naturally occurring protein to which the drug binds," however it is the position of the examiner that the polypeptides of '713 are equivalent to the synthetic peptides of the instant application and that the instant application still reads on the Morgen, Jr. et al reference. The instant specification teaches that the synthetic receptors may be polypeptides derived from proteins along with several other alternatives and does not provide any rational for the exclusion of synthetic receptors that are polypeptides derived from proteins such as a demonstration of unexpected results.

Accordingly, based upon the teachings of '713, it would be obvious to one skilled in the art at the time the invention was made to deliver a drug via a prodrug complex where the drug is bound to a polymeric carrier such that the drug would not dissociate during in vivo administration, but would maintain its activity by preferentially binding to its pathophysiologic receptor over the polymeric carrier with the expected result of reducing the drug's toxicity.

Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until

after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Todd Ware whose telephone number is (703) 305-1700. The examiner can normally be reached on Monday through Friday from 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235 or 308-1234.

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

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11/5/99